Complete Summary

GUIDELINE TITLE

Dementia: supporting people with dementia and their carers in health and social care.

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health, Social Care Institute for Excellence (SCIE), National Institute for Health and Clinical Excellence (NICE). Dementia: supporting people with dementia and their carers in health and social care. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006. 417 p. (National clinical practice guideline; no. 42). [801 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 16, 2008 - Antiepileptic drugs: The U.S. Food and Drug Administration (FDA) has completed its analysis of reports of suicidality (suicidal behavior or ideation [thoughts]) from placebo-controlled clinical trials of drugs used to treat epilepsy, psychiatric disorders, and other conditions. Based on the outcome of this review, FDA is requiring that all manufacturers of drugs in this class include a Warning in their labeling and develop a Medication Guide to be provided to patients prescribed these drugs to inform them of the risks of suicidal thoughts or actions. FDA expects that the increased risk of suicidality is shared by all antiepileptic drugs and anticipates that the class labeling change will be applied broadly.
- June 17, 2008 - Antipsychotics (conventional and atypical]): The U.S. Food and Drug Administration (FDA) notified healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis. The prescribing information for all antipsychotic drugs will now include information about the increased risk of death in the BOXED WARNING and WARNING sections.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Dementia, including:

- Alzheimer's disease
- Dementia with Lewy bodies (DLB)
- Frontotemporal dementia
- Vascular dementia
- Mixed dementias

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Neurology
Psychiatry
Psychology

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Hospitals
Nurses

Occupational Therapists
Patients
Pharmacists
Physical Therapists
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments
Social Workers

GUIDELINE OBJECTIVE(S)

To make recommendations for pharmacological treatments and the use of psychological, psychosocial, and service-level interventions

Specifically it aims to:

- Evaluate the role of specific pharmacological agents, psychological and psychosocial interventions in the treatment and management of dementia
- Evaluate the role of specific services and systems for providing those services in the treatment and management of dementia
- Integrate the above to provide best practice advice on the care of individuals with a diagnosis of dementia through the different phases of illness, including the initiation of treatment, the treatment of acute episodes, and the promotion of well-being
- Consider economic aspects of various interventions for dementia

The guideline does not cover treatments that are not normally available on the National Health Service (NHS) or provided by social care services.

TARGET POPULATION

People of all ages who suffer from dementia and their carers

INTERVENTIONS AND PRACTICES CONSIDERED

1. Coordination and integration of health and social care for people with dementia
2. Risk factor assessment, prevention, and early identification of dementia
3. Diagnosis and assessment of dementia
    - Structural imaging including magnetic resonance imaging (MRI) or computed tomography (CT) scanning
    - Additional diagnostic assessments to distinguish dementia subtypes
    - Electroencephalography (specifically not recommended)
    - Provision of memory assessment services
4. Promoting and maintaining independence in people with dementia
5. Interventions for cognitive symptoms and maintenance of function
    - Non-pharmacological interventions for cognitive symptoms and maintaining function
    - Pharmacological intervention for the cognitive symptoms of Alzheimer's disease
        - Donepezil

        - Galantamine
        - Rivastigmine
        - Memantine (not recommended routinely)
    - Pharmacological interventions for the cognitive symptoms of non-Alzheimer's dementia and mild cognitive impairment (not recommended routinely)

6. Interventions for non-cognitive symptoms and behaviour that challenges
    - Non-pharmacological interventions for non-cognitive symptoms and maintaining function
    - Pharmacological intervention for the non-cognitive symptoms and behavior that challenges
    - Urgent treatment of behavior that challenges
7. Interventions for comorbid emotional disorders
    - Psychological interventions for depression and anxiety
    - Pharmacological interventions for depression
8. Admission to inpatient dementia services
9. Palliative care and end-of-life issues
10. Pain management
11. Support and interventions for carers

MAJOR OUTCOMES CONSIDERED

- Side effects of pharmacological therapy
- Cost-effectiveness
- Sensitivity and specificity of diagnostic tests
- Quality of life
- Psychological well-being
- Neuropsychiatric symptoms
- Maintenance of independent living

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Systematic Literature Review

The aim of the literature review was to systematically identify and synthesise relevant evidence from the literature in order to answer the specific key questions developed by the Guideline Development Group (GDG).

For questions that could best be addressed by qualitative evidence (in particular, experiences of people with dementia and their carers of the support he/she receives from health and social care services), a separate review process was

developed that ran in parallel to the review of other types of evidence (see Section 3.6 of the original full-length version of the guideline for details of this review).

Methodology

A stepwise, hierarchical approach was taken to locating and presenting evidence to the GDG. The National Collaborating Centre for Mental Health (NCCMH) developed this process based on methods set out in *Guideline Development Methods: Information for National Collaborating Centres and Guideline Developers* and after considering recommendations from a range of other sources. These included:

- Clinical Policy and Practice Program of the New South Wales Department of Health (Australia)
- Clinical Evidence online
- The Cochrane Collaboration
- Health Development Agency
- New Zealand Guidelines Group
- National Health Service (NHS) Centre for Reviews and Dissemination
- Oxford Centre for Evidence-Based Medicine
- Scottish Intercollegiate Guidelines Network (SIGN)
- Social Care Institute of Excellence
- United States Agency for Healthcare Research and Quality
- Oxford Systematic Review Development Programme
- Grading of Recommendations: Assessment, Development and Evaluation (GRADE) Working Group

Standard Electronic Databases Searched

The following standard health-related bibliographic databases were searched for relevant evidence:

- CINAHL
- EMBASE
- MEDLINE
- PsycINFO
- Cochrane

The Search Strategy for Questions Concerning Interventions

For questions related to interventions, the initial evidence base was formed from well-conducted randomised controlled trials (RCTs) that addressed at least one of the key questions. Although there are a number of difficulties with the use of RCTs in the evaluation of interventions in health and social care, the RCT remains the most important method for establishing treatment efficacy. For harm-related outcomes and for questions not directly related to interventions, searches were conducted for the appropriate study design (see Text Box 2 in the original full-length guideline document).

Where appropriate, the following databases were searched in addition to the standard databases listed above: Age Info, Age Line, ASSIA, Care Data, Social Services Abstracts, Social Work Abstracts, SSCI, AMED, BNI, CENTRAL, HMIC.

Where the evidence base was large, recent high-quality English-language systematic reviews were used primarily as a source of RCTs (see Appendix 9 in the original full-length guideline document for quality criteria used to assess systematic reviews). However, in some circumstances existing data sets were utilised. Where this was the case, data were cross-checked for accuracy before use. New RCTs meeting inclusion criteria set by the GDG were incorporated into the existing reviews and fresh analyses performed.

After the initial search results were scanned liberally to exclude irrelevant papers, the review team used a purpose-built 'study information' database to manage both the included and the excluded studies (eligibility criteria were developed after consultation with the GDG). For questions without good quality evidence (after the initial search), a decision was made by the GDG about whether to conduct a new search for lower levels of evidence or adopt a consensus process.

In addition, searches were made of the reference lists of all eligible systematic reviews and included studies, as well as the list of evidence submitted by stakeholders. Known experts in the field (see Appendix 5 in the original full-length guideline document), based both on the references identified in early steps and on advice from GDG members, were sent letters requesting relevant studies that were in the process of being published. In addition, the tables of contents of appropriate journals were periodically checked for relevant studies.

The Search Strategy for Questions of Diagnosis and Prognosis

For questions related to diagnosis and prognosis, the search strategy was the same as described above, except that the initial evidence base was formed from systematic reviews of studies with the most appropriate and reliable design to answer the particular question. That is, for questions about diagnosis, cross-sectional studies are most appropriate; for questions about prognosis, cohort studies of representative patients are most appropriate. In situations where it was not possible to identify systematic reviews that directly addressed each key question, a consensus process was adopted (see Section 3.5.6 of the original full-length guideline document).

Search Filters

Search filters developed by the review team consisted of a combination of subject heading and free-text phrases. Specific filters were developed for the guideline topic and, where necessary, for each key question. In addition, the review team used filters developed for systematic reviews, RCTs and other appropriate research designs (see Appendix 14 of the original full-length guideline document).

Study Selection

All primary-level studies included after the first scan of citations were acquired in full and re-evaluated for eligibility at the time they were being entered into the

study information database. Specific eligibility criteria were developed for each key question and are described in the relevant review protocol (see Appendix 13 of the original full-length guideline document). Eligible systematic reviews and primary-level studies were critically appraised for methodological quality (see Appendix 9 of the original full-length guideline document). The eligibility of each study was confirmed by at least one member of the appropriate topic group.

For some key questions, it was necessary to prioritise the evidence with respect to the UK context (that is, external validity). To make this process explicit, the topic groups took into account the following factors when assessing the evidence:

- Participant factors (for example, gender, age, ethnicity)
- Provider factors (for example, model fidelity, the conditions under which the intervention was performed, the availability of experienced staff to undertake the procedure)
- Cultural factors (for example, differences in standard care, differences in the welfare system)

It was the responsibility of each topic group to decide which prioritisation factors were relevant to each key question in light of the UK context and then decide how they should modify their recommendations.

Unpublished Evidence

The GDG used a number of criteria when deciding whether or not to accept unpublished data. First, the evidence must be accompanied by a trial report containing sufficient detail to properly assess the quality of the data. Second, the evidence must be submitted with the understanding that data from the study and a summary of the study's characteristics will be published in the full guideline. However, the GDG recognised that unpublished evidence submitted by investigators might later be retracted by those investigators if the inclusion of such data would jeopardise publication of their research.

Health Economics Review Search Strategy

For the systematic review of the economic evidence on dementia, the standard mental-health-related bibliographic databases (EMBASE, MEDLINE, CINAHL, PsychINFO, HTA) were searched. For these databases, a health economics search filter adapted from the Centre for Reviews and Dissemination (CRD) at the University of York was used in combination with the general filter for dementia. The subject filter employed a combination of free-text terms and medical subject headings, with the subject headings having been exploded. Additional searches were performed in specific health economic databases (NHS EED, OHE HEED). HTA and NHS EED databases were accessed via the Cochrane Library, using the general filter for dementia. OHE HEED was searched using a shorter, database-specific strategy. Initial searches were carried out between December 2004 and March 2005. The searches were updated regularly, with the final search 6 weeks before the consultation period. Search strategies used for the health economics systematic review are provided in Appendix 14 of the original full-length guideline document.

In parallel to searches of electronic databases, reference lists of eligible studies and relevant reviews were searched by hand, and experts in the field of dementia and mental health economics were contacted in order to identify additional published and unpublished work relevant to the guideline. Studies included in the clinical review were also assessed for economic evidence.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence for Intervention Studies

1++ High quality meta-analyses, systematic review of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+ Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1- Meta-analyses, systematic review of RCTs, or RCTs with a high risk of bias*

2++ High quality case control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+ Well conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2- Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal*

3 Non-analytic studies (for example, case reports, case series)

4 Expert opinion, consensus methods

*Studies with a level of evidence "-" should not be used as a basis for making a recommendation.

Hierarchy of Evidence for Studies of the Accuracy of Diagnostic Tests

Ia Systematic review (with homogeneity)* of level I studies**

Ib Level I studies**

II Level II studies***

Systematic reviews of level II studies

III Level III studies****

Systematic reviews of level III studies

IV Evidence obtained from expert committee reports or opinions and/or clinical experiences without critical experience, based on physiology, bench research or 'first principles'

*Homogeneity means there are no, or minor, variations in the directions and degrees of results between individual studies that are included in the systematic review.

**Level I studies:

- That use a blind comparison of the test with a validated reference standard (gold standard)

  and

- In a sample of patients that reflects the population to whom the test would apply.

***Level II studies are studies that have **only one** of the following:

- Narrow population (the sample does not reflect the population to whom the test would apply)
- A poor reference standard (defined as that where the 'test' is included in the 'reference', or where the 'testing' affects the ' reference'
- Non-blind comparison between the test and reference standard
- Case-control studies

****Level III studies are studies that have **at least two or three** of the features listed above

Adapted from *The Guidelines Manual*. Available from: www.nice.org.uk.

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Synthesising the Evidence

Where possible, meta-analysis was used to synthesise the evidence using Review Manager (Review Manager 4.2.8, The Cochrane Collaboration, Copenhagen) or Comprehensive Meta-Analysis (Comprehensive Meta Analysis 2.2.023, BioStat). If necessary, reanalyses of the data or sub-analyses were used to answer key questions not addressed in the original studies or reviews.

For a given outcome (continuous and dichotomous), where more than 50% of the number randomised to any group were not accounted for by trial authors, the data were excluded from the review because of the risk of bias. However, where

possible, dichotomous efficacy outcomes were calculated on an intention-to-treat basis (that is, a 'once-randomised-always-analyse' basis). This assumes that those participants who ceased to engage in the study – from whatever group – had an unfavourable outcome. This meant that the 50% rule was not applied to dichotomous outcomes where there was good evidence that those participants who ceased to engage in the study were likely to have an unfavourable outcome (in this case, early withdrawals were included in both the numerator and denominator). Adverse effects were entered into Review Manager as reported by the study authors because it was usually not possible to determine if early withdrawals had an unfavourable outcome. For the outcome 'leaving the study early for any reason,' the denominator was the number randomised.

The number needed to treat for benefit (NNTB) or the number needed to treat for harm (NNTH) was reported for each outcome where the baseline risk (that is, control group event rate) was similar across studies. In addition, NNTs calculated at follow-up were only reported where the length of follow-up was similar across studies. When the length of follow-up or baseline risk varies (especially with low risk), the NNT is a poor summary of the treatment effect.

Included/excluded studies tables, generated automatically from the study information database, were used to summarise general information about each study (see Appendix 15 of the original full-length guideline document). Where meta-analysis was not appropriate and/or possible, the reported results from each primary-level study were also presented in the included studies table (and included, where appropriate, in a narrative review).

Consultation was used to overcome difficulties with coding. Data from studies included in existing systematic reviews were extracted independently by one reviewer and cross-checked with the existing data set. Where possible, two independent reviewers extracted data from new studies. Where double data extraction was not possible, data extracted by one reviewer was checked by the second reviewer. Disagreements were resolved with discussion. Where consensus could not be reached, a third reviewer resolved the disagreement. Masked assessment (that is, blind to the journal from which the article comes, the authors, the institution, and the magnitude of the effect) was not used since it is unclear that doing so reduces bias.

Presenting the Data to the GDG

Summary characteristics tables and, where appropriate, forest plots generated with Review Manager, were presented to the GDG in order to prepare an evidence profile for each review and to develop recommendations.

Evidence Profile Tables

An evidence profile table was used to summarise both the quality of the evidence and the results of the evidence synthesis (see Appendix 16 of the original full-length guideline document). Each table included a list of studies used in the analysis; a quality assessment of the included studies, which was categorised by the level of evidence (see Appendix 9 of the original full-length guideline document for the quality checklists and Section 3.5.5 of the original full-length guideline document for further information about levels of evidence); information

about the consistency of the evidence (see below for how consistency was measured); and the directness of the evidence (directness refers to how closely the outcome measures, interventions and participants match those of interest). The four components (study design/quality, consistency and directness) were used to produce an overall quality of evidence grade. The following definitions were used:

- High = Further research is very unlikely to change the confidence in the estimate of the effect.
- Moderate = Further research is likely to have an important impact on our confidence in the estimate of the effect and may change the estimate.
- Low = Further research is very likely to have an important impact on our confidence in the estimate of the effect and is likely to change the estimate.
- Very low = Any estimate of effect is very uncertain.

Also included in the evidence profile table was a summary of the findings. Once the evidence profile tables relating to a particular key question were completed, the topic-group lead produced a narrative evidence summary. For the purpose of presenting the evidence in the body of the full guideline, evidence summary tables were produced, which provided summary statistics from only the key outcomes.

Forest Plots

Forest plots were used to present the results of the meta-analyses to the GDG (see Appendix 20 of the original full-length guideline document). Each forest plot displayed the effect size and confidence interval (CI) for each study as well as the overall summary statistic. The graphs were generally organised so that the display of data in the area to the left of the 'line of no effect' indicated a favourable outcome for the treatment in question. Dichotomous outcomes were presented as relative risks (RR) with the associated 95% CI (for an example, see Figure 1 of the original full-length guideline document).

The CI shows with 95% certainty the range within which the true treatment effect should lie and can be used to determine statistical significance. If the CI does not cross the 'line of no effect', the effect is statistically significant.

Continuous outcomes were analysed as weighted mean differences (WMD), or as standardised mean differences (SMD) when different measures were used in different studies to estimate the same underlying effect (for an example, see Figure 2 of the original full-length guideline document). If provided, intention-to-treat data, using a method such as last observation carried forward (LOCF), were preferred over data from completers.

To check for consistency between studies, both the I^2 test of heterogeneity and a visual inspection of the forest plots were used. The I^2 statistic describes the proportion of total variation in study estimates that is due to statistical heterogeneity. Unlike Cochran's chi-squared test, which is often used to indicate the extent of heterogeneity, the I^2 statistic is independent of the number of studies and the treatment-effect metric. An I^2 of less than 30% was taken to indicate mild heterogeneity and a fixed effects model was used to synthesise the results. An I^2 of more than 50% was taken as notable heterogeneity. In this case, an attempt was made to explain the variation (for example, outliers were

removed from the analysis, or subanalyses were conducted to examine the possibility of moderators). If studies with heterogeneous results were found to be comparable, a random-effects model was used to summarise the results. In the random-effects analysis, heterogeneity is accounted for both in the width of confidence intervals and in the estimate of the treatment effect. With decreasing heterogeneity, the random effects approach moves asymptomatically towards a fixed-effects model. An I^2 of 30 to 50% was taken to indicate moderate heterogeneity. In this case, both the chi-squared test of heterogeneity and a visual inspection of the forest plot were used to decide between a fixed and random-effects model.

To explore the possibility that the results entered into each meta-analysis suffered from publication bias, data from included studies were entered; where there was sufficient data, into a funnel plot. Asymmetry of the plot was taken to indicate possible publication bias and investigated further.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Guideline Development Group (GDG)

The GDG consisted of clinical and academic experts in old age psychiatry and geriatric medicine, clinical psychology, nursing, social work, occupational therapy and general practice, a person with dementia and representatives from a service-user organisation. The perspectives of people with dementia and their carers were provided through the full participation of a person with dementia and two carers in the guideline development process and a qualitative review of user experience. The guideline development process was supported by staff from the National Collaborating Centre for Mental Health (NCCMH), who undertook the literature searches, reviewed and presented the evidence to the GDG, managed the process and contributed to drafting the guideline.

Guideline Development Group Meetings

Twenty GDG meetings were held between 8 September 2004 and 6 October 2006. During day-long GDG meetings, in a plenary session, key questions and health/social care and economic evidence were reviewed and assessed, and recommendations formulated. At each meeting, all GDG members declared any potential conflict of interest, and the concerns of the person with dementia and the carers were routinely discussed as part of a standing agenda.

Forming the Evidence Summaries and Recommendations

The included study tables, forest plots and evidence profiles formed the basis for developing the evidence summaries and recommendations.

For intervention studies, quality assessment was conducted using Scottish Intercollegiate Guidelines Network (SIGN) methodology and classified according to a hierarchy (see "Rating Scheme for the Strength of the Evidence" field in this summary).

For studies reporting diagnostic tests of accuracy, the review team used a hierarchy developed by National Institute for Health and Clinical Excellence (NICE) that takes into account the various factors likely to affect the validity of these studies (See "Rating Scheme for the Strength of the Recommendations" in this summary).

Once the evidence profile tables and evidence summaries were finalised and agreed by the GDG, recommendations were developed, taking into account factors from the evidence including trade-offs between the benefits and risks of treatment. Other important factors that were considered in developing recommendations included economic considerations, values of the development group and society, and the group's awareness of practical issues.

Method Used to Answer a Key Question in the Absence of Appropriately Designed, High-Quality Research

In the absence of level I evidence (or a level that is appropriate to the question), or where the GDG were of the opinion (on the basis of previous searches or their knowledge of the literature) that there was unlikely to be such evidence, a consensus process was adopted. This process focused on those questions that the GDG considered a priority.

Consensus of the GDG

The starting point for the process of consensus was that a member of the topic group identified, with help from the systematic reviewer, a narrative review that most directly addressed the key question. Where this was not possible, a brief review of the recent literature was initiated.

This existing narrative review or new review was used as a basis for beginning an iterative process to identify lower levels of evidence relevant to the key question and to lead to written statements for the guideline. The process involved a number of steps:

1. A description of what is known about the issues concerning the key question was written by one of the topic group members.
2. Evidence from the existing review or new review was then presented in narrative form to the GDG and further comments were sought about the evidence and its perceived relevance to the key question.
3. Based on the feedback from the GDG, additional information was sought and added to the information collected. This may include studies that did not directly address the key question but were thought to contain relevant data.
4. If, during the course of preparing the report, a significant body of primary level studies (of appropriate design to answer the question) were identified, a full systematic review was done.
5. At this time, subject possibly to further reviews of the evidence, a series of statements that directly addressed the key question was developed.

6. Following this, on occasions and as deemed appropriate by the development group, the report was then sent to appointed experts outside of the GDG for peer review and comment. The information from this process was then fed back to the GDG for further discussion of the statements.
7. Recommendations were then developed and could also be sent for further external peer review.
8. After this final stage of comment, the statements and recommendations were again reviewed and agreed upon by the GDG.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The economic evidence identified by the health economics systematic review is summarised in the respective chapters of the guideline, following presentation of the clinical and qualitative evidence. The characteristics and results of all economic studies included in the review are provided in the form of evidence tables in Appendix 18 of the original full-length guideline document. Additional economic modeling undertaken alongside the guideline development process is also presented in the relevant chapters.

Further details are provided in the Cost Impact Report (see the "Availability of Companion Documents" field).

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was validated through two consultations.

1. The first draft of the guideline (The full guideline, National Institute for Clinical Excellence [NICE] guideline and Quick Reference Guide) were consulted with Stakeholders and comments were considered by the Guideline Development Group (GDG)
2. The final consultation draft of the Full guideline, the NICE guideline and the Information for the Public were submitted to stakeholders for final comments.

The final draft was submitted to the Guideline Review Panel for review prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

*The designation **NICE TA-2006** indicates that the recommendation is from the National Institute for Clinical Excellence (NICE) technology appraisal on the clinical and cost-effectiveness of donepezil, galantamine and rivastigmine for mild-to-moderate Alzheimer's disease and memantine for moderate-to-severe Alzheimer's disease*.

Principles of Care For People With Dementia

Diversity, Equality and Language

People with dementia should not be excluded from any services because of their diagnosis, age (whether designated too young or too old) or coexisting learning disabilities.

Health and social care staff should treat people with dementia and their carers with respect at all times.

Heath and social care staff should identify the specific needs of people with dementia and their carers arising from diversity, including gender, ethnicity, age (younger or older), religion and personal care. Care plans should record and address these needs.

Health and social care staff should identify the specific needs of people with dementia and their carers arising from ill health, physical disability, sensory impairment, communication difficulties, problems with nutrition, poor oral health and learning disabilities. Care plans should record and address these needs.

Health and social care staff, especially in residential settings, should identify and, wherever possible, accommodate the preferences of people with dementia and their carers, including diet, sexuality and religion. Care plans should record and address these preferences.

People who are suspected of having dementia because of evidence of functional and cognitive deterioration, but who do not have sufficient memory impairment to be diagnosed with the condition, should not be denied access to support services.

If language or acquired language impairment is a barrier to accessing or understanding services, treatment and care, health and social care professionals should provide the person with dementia and/or their carer with:

- Information in the preferred language and/or in an accessible format
- Independent interpreters
- Psychological interventions in the preferred language

Younger People With Dementia

Younger people with dementia have special requirements, and specialist multidisciplinary services should be developed, allied to existing dementia services, to meet their needs for assessment, diagnosis and care.

People With a Learning Disability

Health and social care staff working in care environments where younger people are at risk of developing dementia, such as those catering for people with learning disabilities, should be trained in dementia awareness.

People with learning disabilities and those supporting them should have access to specialist advice and support regarding dementia.

Ethics, Consent and Advance Decision Making

Health and social care professionals should always seek valid consent from people with dementia. This should entail informing the person of options, and checking that he or she understands, that there is no coercion and that he or she continues to consent over time. If the person lacks the capacity to make a decision, the provisions of the Mental Capacity Act 2005 must be followed.

Health and social care professionals should inform people with dementia and their carers about advocacy services and voluntary support, and should encourage their use. If required, such services should be available for both people with dementia and their carers independently of each other.

People with dementia should be given the opportunity to convey information to health and social care professionals involved in their care in a confidential manner. Professionals should discuss with the person any need for information to be shared with colleagues and/or other agencies. Only in exceptional circumstances should confidential information be disclosed to others without the person's consent. However, as dementia worsens and the person becomes more dependent on family or other carers, decisions about sharing information should be made in the context of the Mental Capacity Act 2005 and its Code of Practice. If information is to be shared with others, this should be done only if it is in the best interests of the person with dementia.

Health and social care professionals should discuss with the person with dementia, while he or she still has capacity, and his or her carer the use of:

- Advance statements (which allow people to state what is to be done if they should subsequently lose the capacity to decide or to communicate)
- Advance decisions to refuse treatment (Under the provisions of the Mental Capacity Act 2005)
- Lasting Power of Attorney (a legal document that allows people to state in writing who they want to make certain decisions for them if they cannot make them for themselves, including decisions about personal health and welfare [Under the provisions of the Mental Capacity Act 2005])
- A Preferred Place of Care Plan (which allows people to record decisions about future care choices and the place where the person would like to die [see www.cancerlancashire.org.uk/ppc.html])

Impact of Dementia on Personal Relationships

At the time of diagnosis and when indicated subsequently, the impact of dementia on relationships, including sexual relationships, should be assessed in a sensitive

manner. When indicated, people with dementia and/or their partner and/or carers should be given information about local support services.

Risk of Abuse and Neglect

Because people with dementia are vulnerable to abuse and neglect, all health and social care staff supporting them should receive information and training about, and abide by the local multi-agency policy on, adult protection.

Management and Coordination of Care

Health and social care staff should ensure that care of people with dementia and support for their carers is planned and provided within the framework of care management/coordination (Care management/care coordination involves four elements: the coordination of a full assessment, agreeing a care plan, arranging action to deliver services, and reviewing changing needs within the framework of the single assessment process).

Care managers and care coordinators should ensure that care plans are based on an assessment of the person with dementia's life history, social and family circumstance, and preferences, as well as their physical and mental health needs and current level of functioning and abilities.

Care managers and care coordinators should ensure the coordinated delivery of health and social care services for people with dementia. This should involve:

- A combined care plan agreed by health and social services that takes into account the changing needs of the person with dementia and his or her carers
- Assignment of named health and/or social care staff to operate the care plan
- Endorsement of the care plan by the person with dementia and/or carers
- Formal reviews of the care plan, at a frequency agreed between professionals involved and the person with dementia and/or carers and recorded in the notes. (Time periods for review of care plans are stipulated by Care Programme Approach guidance and the Department of Health [2003])

Funding Arrangements for Health and Social Care

Care managers/care coordinators should explain to people with dementia and their carers that they have the right to receive direct payments and individual budgets (where available). If necessary, people with dementia and their carers should be offered additional support to obtain and manage these.

People with dementia and their carers should be informed about the statutory difference between NHS care and care provided by local authority social services (adult services) so that they can make informed decisions about their eligibility for NHS Continuing Care.

Training and Development of Health and Social Care Staff

Health and social care managers should ensure that all staff working with older people in the health, social care and voluntary sectors have access to dementia-

care training (skill development) that is consistent with their roles and responsibilities.

When developing educational programmes for different health and social care staff, trainers should consider the following elements, combined according to the needs of the staff being trained (if staff care for people with learning disabilities, the training package should be adjusted accordingly).

- Early signs and symptoms suggestive of dementia and its major subtypes.
- The natural history of the different types of dementia, the main signs and symptoms, the progression and prognosis, and the consequences for the person with dementia and his or her carers, family and social network.
- The assessment and pharmacological treatment of dementia including the administration of medication and monitoring of side effects.
- Applying the principles of person-centred care when working with people with dementia and their carers; particular attention should be paid to respect, dignity, learning about each person's life story, individualising activities, being sensitive to individuals' religious beliefs and spiritual and cultural identity, and understanding behaviour that challenges as a communication of unmet need.
- The importance of and use of communication skills for working with people with dementia and their carers; particular attention should be paid to pacing of communication, non-verbal communication and the use of language that is non-discriminatory, positive, and tailored to an individual's ability.
- Assertive outreach techniques to support people who may not be engaged with services.
- A clear description of the roles of the different health and social care professionals, staff and agencies involved in the delivery of care to people with dementia and basic advice on how they should work together in order to provide a comprehensive service.
- Basic introduction to local adult protection policy and procedures, including the reporting of concerns or malpractice and, in particular, who to contact.
- The palliative care approach.

Managers of local mental health and learning disability services should set up consultation and communication channels for care homes and other services for people with dementia and their carers.

Liaison teams from local mental health and learning disability services should offer regular consultation and training for healthcare professionals in acute hospitals who provide care for people with dementia. This should be planned by the acute hospital trust in conjunction with mental health, social care and learning disability services.

Evidence-based educational interventions, such as decision-support software and practice-based workshops, to improve the diagnosis and management of dementia should be made widely available and implemented in primary care.

Environmental Design for People with Dementia

When organising and/or purchasing living arrangements or care home placements for people with dementia, health and social care managers should ensure that the design of built environments meets the needs of people with dementia and

complies with the Disability Discrimination Acts 1995 and 2005, because dementia is defined as a disability within the meaning of the Acts.

When organising and/or purchasing living arrangements and/or care home placements for people with dementia, health and social care managers should ensure that built environments are enabling and aid orientation. Specific, but not exclusive, attention should be paid to: lighting, colour schemes, floor coverings, assistive technology, signage, garden design, and the access to and safety of the external environment.

When organising and/or purchasing living arrangements and/or care home placements for people with dementia, health and social care managers should pay careful consideration to the size of units, the mix of residents, and the skill mix of staff to ensure that the environment is supportive and therapeutic.

Care for People With Dementia in an Acute Hospital Facility

Acute and general hospital trusts should plan and provide services that address the specific personal and social care needs and the mental and physical health of people with dementia who use acute hospital facilities for any reason.

Acute trusts should ensure that all people with suspected or known dementia using inpatient services are assessed by a liaison service that specialises in the treatment of dementia. Care for such people in acute trusts should be planned jointly by the trust's hospital staff, liaison teams, relevant social care professionals and the person with suspected or known dementia and his or her carers.

Integrated Health and Social Care

Health and social care staff should use the Department of Health's publication 'Everybody's business. Integrated mental health services for older adults: a service development guide' (www.everybodysbusiness.org.uk) in conjunction with this guideline as a framework for the planning, implementation and delivery of:

- Primary care
- Home care
- Mainstream and specialist day services
- Sheltered and extra-care housing
- Assistive technology and telecare
- Mainstream and specialist residential care
- Intermediate care and rehabilitation
- Care in general hospitals
- Specialist mental health services, including community mental health teams, memory assessment services, psychological therapies and inpatient care

Health and social care managers should coordinate and integrate working across all agencies involved in the treatment and care of people with dementia and their carers, including jointly agreeing written policies and procedures. Joint planning should include local service users and carers in order to highlight and address problems specific to each locality.

Health and social care professionals should ensure that people with dementia and their carers are given up-to-date information on local arrangements (including inter-agency working) for health and social care, including the independent and voluntary sectors, and on how to access such services.

Risk Factors, Prevention and Early Identification

Risk Factors, Screening and Genetic Counselling

General population screening for dementia should not be undertaken.

In middle-aged and older people, vascular and other modifiable risk factors for dementia (for example, smoking, excessive alcohol consumption, obesity, diabetes, hypertension and raised cholesterol) should be reviewed and, if appropriate, treated.

Healthcare professionals working with people likely to have a genetic cause for their dementia (for example, familial autosomal dominant Alzheimer's disease or frontotemporal dementia, cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy [CADASIL], or Huntington's disease) should offer to refer them and their unaffected relatives for genetic counselling.

Regional genetic services should provide genetic counselling to people who are likely to have a genetic cause for their dementia and their unaffected relatives.

If a genetic cause for dementia is not suspected, including late-onset dementia, genotyping should not be undertaken for clinical purposes.

Preventive Measures

The following interventions should not be prescribed as specific treatments for the primary prevention of dementia:

- Statins
- Hormone replacement therapy
- Vitamin E
- Non-steroidal anti-inflammatory drugs

For the secondary prevention of dementia, vascular and other modifiable risk factors (for example, smoking, excessive alcohol consumption, obesity, diabetes, hypertension and raised cholesterol) should be reviewed in people with dementia, and if appropriate, treated.

Early Identification of Dementia

Primary healthcare staff should consider referring people who show signs of mild cognitive impairment (MCI) for assessment by memory assessment services to aid early identification of dementia, because more than 50% of people with MCI later develop dementia. (Mild cognitive impairment is a syndrome defined as cognitive decline greater than expected for an individual's age and education level, which

does not interfere notably with activities of daily living. It is not a diagnosis of dementia of any type, although it may lead to dementia in some cases.)

Those undertaking health checks as part of health facilitation for people with learning disabilities should be aware of the increased risk of dementia in this group. Those undertaking health checks for other high-risk groups, for example those who have had a stroke and those with neurological conditions such as Parkinson's disease, should also be aware of the possibility of dementia.

Memory assessment services that identify people with MCI (including those without memory impairment, which may be absent in the earlier stages of non-Alzheimer's dementias) should offer follow-up to monitor cognitive decline and other signs of possible dementia in order to plan care at an early stage.

Diagnosis and Assessment of Dementia

Recognition

A diagnosis of dementia should be made only after a comprehensive assessment, which should include:

- History taking
- Cognitive and mental state examination
- Physical examination and other appropriate investigations
- A review of medication in order to identify and minimise use of drugs, including over-the-counter products, that may adversely affect cognitive functioning

People who are assessed for the possibility of dementia should be asked if they wish to know the diagnosis and with whom this should be shared.

Clinical cognitive assessment in those with suspected dementia should include examination of attention and concentration, orientation, short and long-term memory, praxis, language and executive function. As part of this assessment, formal cognitive testing should be undertaken using a standardised instrument. The Mini Mental State Examination (MMSE) has been frequently used for this purpose, but a number of alternatives are now available, such as the 6-item Cognitive Impairment Test (6-CIT), the General Practitioner Assessment of Cognition (GPCOG) and the 7-Minute Screen. Those interpreting the scores of such tests should take full account of other factors known to affect performance, including educational level, skills, prior level of functioning and attainment, language, and any sensory impairments, psychiatric illness or physical/neurological problems.

Formal neuropsychological testing should form part of the assessment in cases of mild or questionable dementia.

At the time of diagnosis of dementia, and at regular intervals subsequently, assessment should be made for medical comorbidities and key psychiatric features associated with dementia, including depression and psychosis, to ensure optimal management of coexisting conditions.

Investigation

A basic dementia screen should be performed at the time of presentation, usually within primary care. It should include:

- Routine haematology
- Biochemistry tests (including electrolytes, calcium, glucose, and renal and liver function)
- Thyroid function tests
- Serum vitamin B12 and folate levels

Testing for syphilis serology or human immunodeficiency virus (HIV) should not be routinely undertaken in the investigation of people with suspected dementia. These tests should be considered only in those with histories suggesting they are at risk or if the clinical picture dictates.

A midstream urine test should always be carried out if delirium is a possibility.

Clinical presentation should determine whether investigations such as chest X-ray or electrocardiogram are needed.

Cerebrospinal fluid examination should not be performed as a routine investigation for dementia.

Diagnosis of Subtypes

A diagnosis of subtype of dementia should be made by healthcare professionals with expertise in differential diagnosis using international standardised criteria (see Table below).

Table: Diagnostic Criteria for Dementia

Type of Dementia	Diagnostic Criteria
Alzheimer's disease	Preferred criteria: NINCDS/ADRDA. Alternatives include ICD-10 and DSM-IV
Vascular dementia	Preferred criteria: NINDS-AIREN. Alternatives include ICD-10 and DSM-IV
Dementia with Lewy bodies	International Consensus criteria for dementia with Lewy bodies
Frontotemporal dementia	Lund-Manchester criteria, NINDS criteria for frontotemporal dementia

DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, fourth edition; ICD-10, International Classification of Diseases, 10th revision; NINCDS/ADRDA, National Institute of Neurological and Communicative Diseases and Stroke/Alzheimer's Disease and Related Disorders Association; NINDS–AIREN, Neuroepidemiology Branch of the National Institute of Neurological Disorders and Stroke–Association Internationale pour la Recherche et l'Enseignement en Neurosciences.

Structural imaging should be used in the assessment of people with suspected dementia to exclude other cerebral pathologies and to help establish the subtype diagnosis. Magnetic resonance imaging (MRI) is the preferred modality to assist with early diagnosis and detect subcortical vascular changes, although computed tomography (CT) scanning could be used. Specialist advice should be taken when interpreting scans in people with learning disabilities.

Perfusion hexamethylpropyleneamine oxime (HMPAO) single-photon emission computed tomography (SPECT) should be used to help differentiate Alzheimer's disease, vascular dementia and frontotemporal dementia if the diagnosis is in doubt. People with Down's syndrome may show SPECT abnormalities throughout life that resemble those in Alzheimer's disease, so this test is not helpful in this group.

If HMPAO SPECT is unavailable, 2-[18F]fluoro-2-deoxy-d-glucose positron emission tomography (FDG PET) should be considered to help differentiate between Alzheimer's disease, vascular dementia and frontotemporal dementia if the diagnosis is in doubt.

Dopaminergic iodine-123-radiolabelled 2beta-carbomethoxy-3beta-(4-iodophenyl)-N-(3-fluoropropyl) nortropane (FP-CIT) SPECT should be used to help establish the diagnosis in those with suspected dementia with Lewy bodies (DLB) if the diagnosis is in doubt.

Cerebrospinal fluid examination should be used if Creutzfeldt–Jakob disease or other forms of rapidly progressive dementia are suspected.

Electroencephalography should not be used as a routine investigation in people with dementia.

Electroencephalography should be considered if a diagnosis of delirium, frontotemporal dementia or Creutzfeldt–Jakob disease is suspected, or in the assessment of associated seizure disorder in those with dementia.

Brain biopsy for diagnostic purposes should be considered only in highly selected people whose dementia is thought to be due to a potentially reversible condition that cannot be diagnosed in any other way.

Mixed Dementias

Many cases of dementia may have mixed pathology (for example, Alzheimer's disease and vascular dementia or Alzheimer's disease and DLB). Unless otherwise stated in this guideline, such cases should be managed according to the condition that is thought to be the predominant cause of dementia.

Specialist Services for Dementia Assessment

Memory assessment services (which may be provided by a memory assessment clinic or by community mental health teams) should be the single point of referral for all people with a possible diagnosis of dementia.

Memory assessment services should offer a responsive service to aid early identification and should include a full range of assessment, diagnostic, therapeutic, and rehabilitation services to accommodate the needs of people with different types and all severities of dementia and the needs of their carers and family.

Memory assessment services should ensure an integrated approach to the care of people with dementia and the support of their carers, in partnership with local health, social care, and voluntary organisations.

Addressing Needs That Arise From the Diagnosis of Dementia

The experience of the diagnosis of dementia is challenging both for people with dementia and family members and for healthcare professionals, so healthcare professionals should make time available to discuss the diagnosis and its implications with the person with dementia and also with family members (usually only with the consent of the person with dementia). Healthcare professionals should be aware that people with dementia and family members may need ongoing support to cope with the difficulties presented by the diagnosis.

Following a diagnosis of dementia, health and social care professionals should, unless the person with dementia clearly indicates to the contrary, provide them and their family with written information about:

- The signs and symptoms of dementia
- The course and prognosis of the condition
- Treatments
- Local care and support services
- Support groups
- Sources of financial and legal advice, and advocacy
- Medico-legal issues, including driving
- Local information sources, including libraries and voluntary organisations

Any advice and information given should be recorded in the notes.

Healthcare professionals who regularly diagnose dementia and discuss this with people with the condition and carers should consider mentoring or providing clinical supervision to less experienced colleagues.

Promoting and Maintaining Independence of People with Dementia

Health and social care staff should aim to promote and maintain the independence, including mobility, of people with dementia. Care plans should address activities of daily living (ADLs) that maximise independent activity, enhance function, adapt and develop skills, and minimise the need for support. When writing care plans, the varying needs of people with different types of dementia should be addressed. Care plans should always include:

- Consistent and stable staffing
- Retaining a familiar environment
- Minimising relocations

- Flexibility to accommodate fluctuating abilities
- Assessment and care-planning advice regarding ADLs, and ADL skill training from an occupational therapist
- Assessment and care-planning advice about independent toileting skills; if incontinence occurs all possible causes should be assessed and relevant treatments tried before concluding that it is permanent
- Environmental modifications to aid independent functioning, including assistive technology, with advice from an occupational therapist and/or clinical psychologist
- Physical exercise, with assessment and advice from a physiotherapist when needed
- Support for people to go at their own pace and participate in activities they enjoy

When developing a care plan for a person with a learning disability newly diagnosed with dementia, an assessment using the Assessment of Motor and Process Skills (AMPS) (AMPS should be carried out by someone with formal training in its use.) should be considered. The Dementia Questionnaire for Mentally Retarded Persons (DMR) and Dalton's Brief Praxis Test (BPT) should be considered for monitoring change in function over time.

Interventions for Cognitive Symptoms and Maintenance of Function for People With Dementia

Non-Pharmacological Interventions for Cognitive Symptoms AND Maintaining Function

People with mild-to-moderate dementia of all types should be given the opportunity to participate in a structured group cognitive stimulation programme. This should be commissioned and provided by a range of health and social care staff with appropriate training and supervision, and offered irrespective of any drug prescribed for the treatment of cognitive symptoms of dementia.

Pharmacological Interventions for the Cognitive Symptoms of Alzheimer's Disease

Note: This section includes recommendations from the NICE technology appraisal on the clinical and cost-effectiveness of donepezil, galantamine and rivastigmine for mild-to-moderate Alzheimer's disease and memantine for moderate-to-severe Alzheimer's disease (see www.nice.org.uk/TA111). Following NICE protocol, the recommendations have been incorporated verbatim into this guideline (where one of these recommendations appears, it is indicated as NICE TA 2006).

NICE TA 2006 - The three acetylcholinesterase inhibitors donepezil, galantamine and rivastigmine (the guidance applies to the marketing authorisation held for each drug at the time of the appraisal) are recommended as options in the management of people with Alzheimer's disease of moderate severity only (that is, those with an MMSE score of between 10 and 20 points), and under the following conditions.

- Only specialists in the care of people with dementia (that is, psychiatrists including those specialising in learning disability, neurologists, and physicians

specialising in the care of the elderly) should initiate treatment. Carers' views on the patient's condition at baseline should be sought.
- Patients who continue on the drug should be reviewed every 6 months by MMSE score and global, functional and behavioural assessment. Carers' views on the patient's condition at follow-up should be sought. The drug should only be continued while the patient's MMSE score remains at or above 10 points and their global, functional and behavioural condition remains at a level where the drug is considered to be having a worthwhile effect. Any review involving MMSE assessment should be undertaken by an appropriate specialist team, unless there are locally agreed protocols for shared care.

Although it is recommended that acetylcholinesterase inhibitors should be prescribed only to people with Alzheimer's disease of moderate severity, healthcare professionals should not rely on the MMSE score in certain circumstances. These are:

- In those with an MMSE score greater than 20, who have moderate dementia as judged by significant impairments in functional ability and personal and social function compared with premorbid ability
- In those with an MMSE score less than 10 because of a low premorbid attainment or ability or linguistic difficulties, who have moderate dementia as judged by an assessment tool sensitive to their level of competence
- In people with learning disabilities
- In people who are not fluent in spoken English or in the language in which the MMSE is applied.

For people with learning disabilities, tools used to assess the severity of dementia should be sensitive to their level of competence.

Options include:

- Cambridge Cognitive Examination (CAMCOG)
- Modified Cambridge Examination for Mental Disorders of the Elderly (CAMDEX)
- DMR
- Dementia Scale for Down Syndrome (DSDS), which can be useful in diagnosis of dementia in people with learning disabilities who do not have Down's syndrome.

NICE TA 2006 - When the decision has been made to prescribe an acetylcholinesterase inhibitor, it is recommended that therapy should be initiated with a drug with the lowest acquisition cost (taking into account required daily dose and the price per dose once shared care has started).However, an alternative acetylcholinesterase inhibitor could be prescribed where it is considered appropriate having regard to adverse event profile, expectations around concordance, medical comorbidity, possibility of drug interactions, and dosing profiles.

NICE TA 2006 - Memantine is not recommended as a treatment option for people with moderately severe to severe Alzheimer's disease except as part of well-designed clinical studies.

NICE TA 2006 - People with mild Alzheimer's disease who are currently receiving donepezil, galantamine or rivastigmine, and people with moderately severe to severe Alzheimer's disease currently receiving memantine, whether as routine therapy or as part of a clinical trial, may be continued on therapy (including after the conclusion of a clinical trial) until they, their carers and/or specialist consider it appropriate to stop.

Pharmacological Interventions for the Cognitive Symptoms of Non-Alzheimer Dementias and MCI

For people with vascular dementia, acetylcholinesterase inhibitors and memantine should not be prescribed for the treatment of cognitive decline, except as part of properly constructed clinical studies.

For people with MCI, acetylcholinesterase inhibitors should not be prescribed, except as part of properly constructed clinical studies.

Interventions for Non-Cognitive Symptoms and Behaviour that Challenges in People With Dementia

Non-Pharmacological Interventions for Non-Cognitive Symptoms and Behaviour That Challenges

People with dementia who develop non-cognitive symptoms that cause them significant distress or who develop behaviour that challenges should be offered an assessment at an early opportunity to establish likely factors that may generate, aggravate or improve such behaviour. The assessment should be comprehensive and include:

- The person's physical health
- Depression
- Possible undetected pain or discomfort
- Side effects of medication
- Individual biography, including religious beliefs and spiritual and cultural identity
- Psychosocial factors
- Physical environmental factors
- Behavioural and functional analysis conducted by professionals with specific skills, in conjunction with carers and care workers

Individually tailored care plans that help carers and staff address the behaviour that challenges should be developed, recorded in the notes and reviewed regularly. The frequency of the review should be agreed by the carers and staff involved and written in the notes.

For people with all types and severities of dementia who have comorbid agitation, consideration should be given to providing access to interventions tailored to the person's preferences, skills and abilities. Because people may respond better to one treatment than another, the response to each modality should be monitored and the care plan adapted accordingly. Approaches that may be considered, depending on availability, include:

- Aromatherapy
- Multisensory stimulation
- Therapeutic use of music and/or dancing
- Animal-assisted therapy
- Massage

These interventions may be delivered by a range of health and social care staff and volunteers, with appropriate training and supervision. The voluntary sector has a particular role to play in delivering these approaches. Health and social care staff in the NHS and social care, including care homes, should work together to ensure that some of these options are available, because there is some evidence of their clinical effectiveness. More research is needed into their cost effectiveness.

Pharmacological Interventions for Non-Cognitive Symptoms and Behaviour that Challenges

People with dementia who develop non-cognitive symptoms or behaviour that challenges should be offered a pharmacological intervention in the first instance only if they are severely distressed or there is an immediate risk of harm to the person or others. The assessment and care-planning approach, which includes behavioural management, should be followed as soon as possible (see above recommendation "Non-Pharmacological Interventions for Non-Cognitive Symptoms and Behaviour that Challenges"). If distress and/or agitation are less severe, the interventions described above in recommendations "Non-Pharmacological Interventions for Non-Cognitive Symptoms and Behaviour that Challenges" and below under "Psychological Interventions for People with Dementia with Depression and/or Anxiety" and "Psychological Interventions for People with Dementia with Depression", should be followed before a pharmacological intervention is considered.

People with Alzheimer's disease, vascular dementia or mixed dementias with mild-to-moderate non-cognitive symptoms should not be prescribed antipsychotic drugs because of the possible increased risk of cerebrovascular adverse events and death. (In March 2004, the Medicines and Healthcare products Regulatory Agency's Committee on Safety of Medicines issued a safety warning about the atypical antipsychotic drugs risperidone and olanzapine, advising that these drugs should not be used for the treatment of behavioural symptoms of dementia. Further information is available from www.mhra.gov.uk.)

People with DLB with mild-to-moderate non-cognitive symptoms, should not be prescribed antipsychotic drugs, because those with DLB are at particular risk of severe adverse reactions.

People with Alzheimer's disease, vascular dementia, mixed dementias or DLB with severe non-cognitive symptoms (psychosis and/or agitated behaviour causing significant distress) may be offered treatment with an antipsychotic drug after the following conditions have been met.

- There should be a full discussion with the person with dementia and/or carers about the possible benefits and risks of treatment. In particular, cerebrovascular risk factors should be assessed and the possible increased

risk of stroke/transient ischaemic attack and possible adverse effects on cognition discussed.
- Changes in cognition should be assessed and recorded at regular intervals. Alternative medication should be considered if necessary.
- Target symptoms should be identified, quantified and documented.
- Changes in target symptoms should be assessed and recorded at regular intervals.
- The effect of comorbid conditions, such as depression, should be considered.
- The choice of antipsychotic should be made after an individual risk–benefit analysis.
- The dose should be low initially and then titrated upwards.
- Treatment should be time limited and regularly reviewed (every 3 months or according to clinical need).

For people with DLB, healthcare professionals should monitor carefully for the emergence of severe untoward reactions, particularly neuroleptic sensitivity reactions (which manifest as the development or worsening of severe extrapyramidal features after treatment in the accepted dose range or acute and severe physical deterioration following prescription of antipsychotic drugs for which there is no other apparent cause).

People with mild, moderate, or severe Alzheimer's disease who have non-cognitive symptoms and/or behaviour that challenges, causing significant distress or potential harm to the individual, may be offered an acetylcholinesterase inhibitor if:

- A non-pharmacological approach is inappropriate or has been ineffective
- Antipsychotic drugs are inappropriate or have been ineffective

People with DLB who have non-cognitive symptoms causing significant distress to the individual, or leading to behaviour that challenges, should be offered an acetylcholinesterase inhibitor.

People with vascular dementia who develop non-cognitive symptoms or behaviour that challenges should not be prescribed acetylcholinesterase inhibitors, except as part of properly constructed clinical studies.

Behaviour that Challenges Requiring Urgent Treatment

Managing Risk

Health and social care staff who care for people with dementia should identify, monitor and address environmental, physical health and psychosocial factors that may increase the likelihood of behaviour that challenges, especially violence and aggression, and the risk of harm to self or others. These factors include:

- Overcrowding
- Lack of privacy
- Lack of activities
- Inadequate staff attention
- Poor communication between the person with dementia and staff

- Conflicts between staff and carers
- Weak clinical leadership

Health and social care staff should be trained to anticipate behaviour that challenges and how to manage violence, aggression and extreme agitation, including de-escalation techniques and methods of physical restraint.

Healthcare professionals who use medication in the management of violence, aggression and extreme agitation in people with dementia should:

- Be trained in the correct use of drugs for behavioural control, specifically benzodiazepines and antipsychotics
- Be able to assess the risks associated with pharmacological control of violence, aggression and extreme agitation, particularly in people who may be dehydrated or physically ill
- Understand the cardiorespiratory effects of the acute administration of benzodiazepines and antipsychotics and the need to titrate dosage to effect
- Recognise the importance of nursing people who have received these drugs in the recovery position and of monitoring pulse, blood pressure and respiration
- Be familiar with and trained in the use of resuscitation equipment
- undertake annual retraining in resuscitation techniques
- Understand the importance of maintaining an unobstructed airway

Principles of Pharmacological Control of Violence, Aggression and Extreme Agitation

For people with dementia who are at significant risk to themselves or others because of violence, aggression and extreme agitation, immediate management should take place in a safe, low-stimulation environment, separate from other service users.

Drug treatments for the control of violence, aggression and extreme agitation should be used to calm the person with dementia and reduce the risk of violence and harm, rather than treat any underlying psychiatric condition. Healthcare professionals should aim for an optimal response in which agitation or aggression is reduced without sedation.

Violent behaviour should be managed without the prescription of high doses or combinations of drugs, especially if the person with dementia is elderly or frail. The lowest effective dose should be used.

Drugs for behavioural control should be used with caution, particularly if the person with dementia has been restrained, because of the following risks:

- Loss of consciousness instead of sedation
- Over-sedation with loss of alertness
- Damage to the relationship between the person with dementia, their carers and the health and social care team
- Specific issues related to age and physical and mental health

People with dementia who have received involuntary sedation and their carers should be offered the opportunity to discuss their experiences and be provided with a clear explanation of the decision to use urgent sedation. This should be documented in their notes.

Route of Drug Administration

If drugs are necessary for the control of violence, aggression and extreme agitation, oral medication should be offered before parenteral medication.

If parenteral treatment is necessary for the control of violence, aggression and extreme agitation, the intramuscular (IM) route should be preferred because it is safer than intravenous administration. Intravenous administration should be used only in exceptional circumstances.

Vital signs should be monitored after parenteral treatment for the control of violence, aggression and extreme agitation. Blood pressure, pulse, temperature and respiratory rate should be recorded at regular intervals agreed by the multidisciplinary team until the person with dementia becomes active again. If the person appears to be or is asleep, more intensive monitoring is required.

Intramuscular Agents for Behavioural Control

If IM preparations are needed for behavioural control, lorazepam, haloperidol or olanzapine should be used. Wherever possible, a single agent should be used in preference to a combination.

If rapid tranquillisation is needed, a combination of IM haloperidol and IM lorazepam should be considered.

IM diazepam and IM chlorpromazine are not recommended for the management of behaviour that challenges in people with dementia.

If using IM haloperidol (or any other IM conventional antipsychotic) for behavioural control, healthcare professionals should monitor closely for dystonia and other extrapyramidal side effects. If side effects become distressing, especially in acute dystonic reactions, the use of anticholinergic agents should be considered. If using anticholinergic agents, healthcare professionals should monitor for deteriorating cognitive function.

Interventions for Comorbid Emotional Disorders in People with Dementia

Psychological Interventions for People with Dementia with Depression and/or Anxiety

Care packages for people with dementia should include assessment and monitoring for depression and/or anxiety.

For people with dementia who have depression and/or anxiety, cognitive behavioural therapy, which may involve the active participation of their carers, may be considered as part of treatment.

A range of tailored interventions, such as reminiscence therapy, multisensory stimulation, animal-assisted therapy and exercise, should be available for people with dementia who have depression and/or anxiety.

Pharmacological Interventions for People with Dementia with Depression

People with dementia who also have major depressive disorder should be offered antidepressant medication. Treatment should be started by staff with specialist training, who should follow the NICE clinical guideline "Depression: management of depression in primary and secondary care" (available from www.nice.org.uk/CG023) after a careful risk–benefit assessment. Antidepressant drugs with anticholinergic effects should be avoided because they may adversely affect cognition. The need for adherence, time to onset of action and risk of withdrawal effects should be explained at the start of treatment.

Inpatient Dementia Services

As far as possible, dementia care services should be community-based, but psychiatric inpatient admission may be considered in certain circumstances, including if:

- The person with dementia is severely disturbed and needs to be contained for his or her own health and safety and/or the safety of others (in some cases, this might include those liable to be detained under the Mental Health Act 1983)
- Assessment in a community setting is not possible, for example if a person with dementia has complex physical and psychiatric problems

Palliative Care, Pain Relief and Care at the End of Life For People With Dementia

Palliative Care and End of Life Issues

Health and social care professionals working with people with dementia and their carers should adopt a palliative care approach. They should consider physical, psychological, social and spiritual needs to maximise the quality of life of the person with dementia and their family.

Palliative care professionals, other health and social care professionals, and commissioners should ensure that people with dementia who are dying have the same access to palliative care services as those without dementia.

Primary care teams should ensure that the palliative care needs of people with dementia who are close to death are assessed and that the resulting information is communicated within the team and with other health and social care staff.

Health and social care staff should encourage people with dementia to eat and drink by mouth for as long as possible. Specialist assessment and advice concerning swallowing and feeding in dementia should be available. Dietary advice may also be beneficial. Nutritional support, including artificial (tube) feeding, should be considered if dysphagia is thought to be a transient phenomenon, but

artificial feeding should not generally be used in people with severe dementia for whom dysphagia or disinclination to eat is a manifestation of disease severity. Ethical and legal principles should be applied when making decisions about withholding or withdrawing nutritional support.

If a person with severe dementia has a fever, especially in the terminal stages, a clinical assessment should be undertaken. Simple analgesics, antipyretics and mechanical means of cooling the person may suffice. Antibiotics may be considered as a palliative measure in the terminal stages of dementia, but this needs an individual assessment.

Policies in hospitals and long-stay residential, nursing or continuing care units should reflect the fact that cardiopulmonary resuscitation is unlikely to succeed in cases of cardiopulmonary arrest in people with severe dementia.

In the absence of a valid and applicable advance decision to refuse resuscitation, the decision to resuscitate should take account of any expressed wishes or beliefs of the person with dementia, together with the views of the carers and the multidisciplinary team. The decision should be made in accordance with the guidance developed by the Resuscitation Council UK and, if the person lacks capacity, the provisions of the Mental Capacity Act 2005. It should be recorded in the medical notes and care plans.

Pain Relief

If a person with dementia has unexplained changes in behaviour and/or shows signs of distress, health and social care professionals should assess whether the person is in pain, using an observational pain assessment tool if helpful. However, the possibility of other causes should be considered.

The treatment of pain in people with severe dementia should involve both pharmacological and non-pharmacological measures. Nonpharmacological therapies should be used with the person's history and preferences in mind.

Support and Interventions for the Carers of People with Dementia

Assessment of Carers' Needs

Health and social care managers should ensure that the rights of carers to receive an assessment of needs, as set out in the Carers and Disabled Children Act 2000 and the Carers (Equal Opportunities) Act 2004, are upheld.

Interventions

Those carrying out carers' assessment should seek to identify any psychological distress and the psychosocial impact on the carer. This should be an ongoing process and should include any period after the person with dementia has entered residential care.

Care plans for carers of people with dementia should involve a range of tailored interventions. These may consist of multiple components including:

- Individual or group psychoeducation
- Peer-support groups with other carers, tailored to the needs of individuals depending on the stage of dementia of the person being cared for and other characteristics
- Support and information by telephone and through the internet
- Training courses about dementia, services and benefits, and communication and problem solving in the care of people with dementia
- Involvement of other family members as well as the primary carer in family meetings

Consideration should be given to involving people with dementia in psychoeducation, support, and other meetings for carers.

Health and social care professionals should ensure that support, such as transport or short-break services, is provided for carers to enable them to participate in interventions.

Carers of people with dementia who experience psychological distress and negative psychological impact should be offered psychological therapy, including cognitive behavioural therapy, conducted by a specialist practitioner.

Practical Support and Services

Health and social care managers should ensure that carers of people with dementia have access to a comprehensive range of respite/shortbreak services. These should meet the needs of both the carer (in terms of location, flexibility and timeliness) and the person with dementia and should include, for example, day care, day- and night-sitting, adult placement and short-term and/or overnight residential care. Transport should be offered to enable access to these services if they are not provided in the person's own home.

Respite/short-break care of any sort should be characterised by meaningful and therapeutic activity tailored to the person with dementia and provided in an environment that meets their needs. Providing this in the person's own home should be considered whenever possible.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of patients with dementia

POTENTIAL HARMS

- Evidence suggests an increase risk of adverse events, particularly anorexia and cramps (although serious adverse events are unlikely) with use of acetylcholinesterase inhibitors. The evidence suggests that at high doses the potential benefits are unlikely to outweigh the increased risk of adverse events. When given at lower doses, adverse events are less likely; therapeutic responses are not diminished, but are still unlikely to outweigh the potential increased risk of adverse events.
- Drugs for behavioural control should be used with caution, particularly if the person with dementia has been restrained, because of the following risks:
    - Loss of consciousness instead of sedation
    - Over-sedation with loss of alertness
    - Damage to the relationship between the person with dementia, their carers and the health and social care team
    - Specific issues related to age and physical and mental health
- Vital signs should be monitored after parenteral treatment for the control of violence, aggression and extreme agitation. Blood pressure, pulse, temperature and respiratory rate should be recorded at regular intervals agreed by the multidisciplinary team until the person with dementia becomes active again. If the person appears to be or is asleep, more intensive monitoring is required.
- Antipsychotic agents may be associated with severe reactions including neuroleptic sensitivity and severe extrapyramidal symptoms.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of National Institute for Health and Clinical Excellence (NICE) and Social Care Institute for Excellence (SCIE), which was arrived at after careful consideration of the evidence available. Health and social care staff are expected to take it fully into account when exercising their professional judgement. The guidance does not, however, override the individual responsibility of health and social care staff to make decisions appropriate to the circumstances of the individual person with dementia, in consultation with the person and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. Implementation of clinical guidelines forms part of the developmental standard D2. Core standard C5 says that national agreed guidance should be taken into account when NHS organisations are planning and delivering care.

Key Priorities for Implementation

Non-discrimination

- People with dementia should not be excluded from any services because of their diagnosis, age (whether designated too young or too old) or coexisting learning disabilities.

Valid Consent

- Health and social care professionals should always seek valid consent from people with dementia. This should entail informing the person of options, and checking that he or she understands, that there is no coercion and that he or she continues to consent over time. If the person lacks the capacity to make a decision, the provisions of the Mental Capacity Act 2005 must be followed.

Carers

- Health and social care managers should ensure that the rights of carers to receive an assessment of needs, as set out in the Carers and Disabled Children Act 2000 and the Carers (Equal Opportunities) Act 2004, are upheld.
- Carers of people with dementia who experience psychological distress and negative psychological impact should be offered psychological therapy, including cognitive behavioural therapy, conducted by a specialist practitioner.

Coordination and Integration of Health and Social Care

- Health and social care managers should coordinate and integrate working across all agencies involved in the treatment and care of people with dementia and their carers, including jointly agreeing written policies and procedures. Joint planning should include local service users and carers in order to highlight and address problems specific to each locality.
- Care managers and care coordinators should ensure the coordinated delivery of health and social care services for people with dementia. This should involve:
    - A combined care plan agreed by health and social services that takes into account the changing needs of the person with dementia and his or her carers
    - Assignment of named health and/or social care staff to operate the care plan
    - Endorsement of the care plan by the person with dementia and/or carers
    - Formal reviews of the care plan, at a frequency agreed between professionals involved and the person with dementia and/or carers and recorded in the notes. (Time periods for review of care plans are stipulated by Care Programme Approach guidance and the Department of Health [2003])

Memory Services

- Memory assessment services (which may be provided by a memory assessment clinic or by community mental health teams) should be the single point of referral for all people with a possible diagnosis of dementia.

Structural Imaging for Diagnosis

- Structural imaging should be used in the assessment of people with suspected dementia to exclude other cerebral pathologies and to help establish the subtype diagnosis. Magnetic resonance imaging (MRI) is the preferred modality to assist with early diagnosis and detect subcortical vascular changes, although computed tomography (CT) scanning could be used. Specialist advice should be taken when interpreting scans in people with learning disabilities.

Behaviour That Challenges

- People with dementia who develop non-cognitive symptoms that cause them significant distress or who develop behaviour that challenges should be offered an assessment at an early opportunity to establish the likely factors that may generate, aggravate or improve such behaviour. The assessment should be comprehensive and include:
    - The person's physical health
    - Depression
    - Possible undetected pain or discomfort
    - Side effects of medication
    - Individual biography, including religious beliefs and spiritual and cultural identity
    - Psychosocial factors
    - Physical environmental factors
    - Behavioural and functional analysis conducted by professionals with specific skills, in conjunction with carers and care workers

Individually tailored care plans that help carers and staff address the behaviour that challenges should be developed, recorded in the notes and carers and staff involved and written in the notes.

Training

- Health and social care managers should ensure that all staff working with older people in the health, social care and voluntary sectors have access to dementia-care training (skill development) that is consistent with their roles and responsibilities.

Mental Health Needs in Acute Hospitals

- Acute and general hospital trusts should plan and provide services that address the specific personal and social care needs and the mental and physical health of people with dementia who use acute hospital facilities for any reason.

Details on implementation can be found in the document "Implementation Advice" (see "Availability of Companion Documents" field in this summary).

Suggested audit criteria are listed in the document "Audit Criteria" (see "Availability of Companion Documents" field in this summary).

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Collaborating Centre for Mental Health, Social Care Institute for Excellence (SCIE), National Institute for Health and Clinical Excellence (NICE). Dementia: supporting people with dementia and their carers in health and social care. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006. 417 p. (National clinical practice guideline; no. 42). [801 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

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GUIDELINE DEVELOPER(S)

National Collaborating Centre for Mental Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Guideline Development Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

At each Guideline Development Group (GDG) meeting, all GDG members declared any potential conflict of interests.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- National Collaborating Centre for Mental Health. Dementia. Supporting people with dementia and their carers in health and social care. NICE guideline (Clinical guideline 42). London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Nov. 56 p. Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- National Collaborating Centre for Mental Health. Dementia. Supporting people with dementia and their carers in health and social care. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Nov. 27 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Dementia. Implementation advice. 2006 Nov. 22 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Dementia. Costing report. Implementing NICE SCIE guidance in England. 2006 Nov. 41 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Dementia: supporting people with dementia and their carers. Costing template. Implementing NICE-SCIE guidance in England. 2006 Nov. Various p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Dementia. Audit criteria. 2006 Nov. 18 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- Dementia. Presenter slides. 2006 Nov. 37 p. Electronic copies: Available in Portable Document Format (PDF) from the NICE Web site.
- The guidelines manual 2006. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 April. Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1144. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Dementia: supporting people with dementia and their carers. Understanding NICE–SCIE guidance. Information for people who use NHS and social care services. National Institute for Health and Clinical Excellence (NICE), 2006 Nov. 19 p. Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1145. 11 Strand, London, WC2N 5HR.

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